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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/537,320	06/02/2005	Akihiro Tada	TOYA107.007APC	3197
20995 7590 07/31/2008 KNOBBE MARTENS OLSON & BEAR LLP 2040 MAIN STREET FOURTEENTH FLOOR IRVINE, CA 92614			EXAMINER SZNAIDMAN, MARCOS L	
			ART UNIT 1611	PAPER NUMBER
			NOTIFICATION DATE 07/31/2008	DELIVERY MODE ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No. 10/537,320	Applicant(s) TADA ET AL.	
	Examiner MARCOS SZNAIDMAN	Art Unit 1611	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 April 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-11 is/are pending in the application.
- 4a) Of the above claim(s) 1-6 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 7-11 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>5 pages 06/02/05 and 02/27/06</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This office action is in response to applicant's reply filed on April 9, 2008.

Election/Restrictions

Applicant's election of Group II (claims 7-11) in the reply filed on April 9, 2008 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Applicant's election with traverse of Centaureidin as the elected species in the reply filed on April 9, 2008 is acknowledged. Applicant's arguments are persuasive, so the election requirement is withdrawn.

Status of Claims

Claims 1-11 are currently pending and are the subject of this office action.

Claims 1-6 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on April 9, 2008.

Claims 7-11 are presently under examination.

Priority

The present application is a 371 of PCT/JP03/15267 filed on 11/28/2003, and claims priority to foreign application JAPAN 2002-350733 filed on 12/03/2002.

Should applicant desire to obtain the benefit of foreign priority under 35 U.S.C. 119(a)-(d) prior to declaration of an interference, a certified English translation of the foreign application must be submitted in reply to this action. 37 CFR 41.154(b) and 41.202(e).

Failure to provide a certified translation may result in no benefit being accorded for the non-English application.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.

3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 7-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ishida et. al. (EP 1147764, cited by applicant).

Claims 7 recites a method, for inhibiting elongation of melanocytic dendrites, comprising: a step of applying a skin preparation for external use, for inhibiting elongation of melanocytic dendrites, comprising, as an active ingredient, a dendrite elongation inhibitor for melanocytes, consisting of a compound represented by formula I (see claim 1).

For claim 7, Ishida et. al. teach a cosmetic composition of general formula I (see page 3, these compounds encompass the compounds of general formula I of the instant application), having a sufficient whitening effect, a so called anti skin-aging effect as vitalizing the skin and preventing wrinkles (see page 2, paragraphs [0006] and [0007]). Ishida et. al. do not teach the compounds encompassed by formula I of the instant application, however Ishida et. al. suggest the compounds of the instant application by choosing the appropriate R substituents in the general formula I (see page 3).

At the time of the invention, it would have been *prima facie* obvious for a person of ordinary skill in the art to apply the teachings of Ishida et. al. (applying to the skin compounds of Formula I for the treatment of skin diseases: skin-aging, skin darkening, wrinkles, etc) to treat skin disorders with compounds of formula I, with the motivation of better treating skin diseases thus resulting in the practice of claim 7 with a reasonable expectation of success.

Regarding the preamble in claim 7: “for inhibiting elongation of melanocytic dendrites”, it is considered a characteristic of the method taught by Ishida et. al. Although Ishida et. al. is silent as to inhibiting elongation of melanocytic dendrites by compounds of formula I, it seems that applicant has discovered a new mechanism of action of compounds of formula I. This mechanism of action would have necessarily be present in the method of Ishida et. al. since the same compounds are being used for the same purpose: skin treatment. In other words, products of identical or similar composition cannot exert mutually exclusive properties when administered under the same circumstances. MPEP 2112 I states: “The discovery of a previously

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unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer". The explanation of an effect or mechanism of action obtained when using a compound (e.g. inhibiting elongation of melanocytic dendrites by compounds of formula I) cannot confer novelty on a known process (applying compounds of formula I to the skin) if the skilled artisan was already aware of the occurrence of the desired therapeutic effect. Though new properties of a compound or their mechanism of action are no doubt important contributions to scientific and pharmaceutical development, the assessment of patentability is based upon the therapeutic applications and effects of the compounds, not the mechanism or properties by which they exert such a therapeutic effect.

Claim 8, further limits claim 7, wherein the compound of formula I is now Centaureidin (see claim 8).

Ishida et. al. teach all the limitations of claim 8, except for the specific compound Centaureidin. Ishida et. al. limit their structure to at least four methoxy groups (see page 3, line 18), while Centaureidin has three methoxy groups. MPEP 2144, Section III states: prior art structures do not have to be true homologs or isomers to render structurally similar compounds *prima facie* obvious. *In re Payne*, 606 F.2d 303, 203 USPQ 245 (CCPA 1979) (Claimed and prior art compounds were both directed to heterocyclic carbamoyloximino compounds having pesticidal activity. The only structural difference between the claimed and prior art was that the ring structures of the

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claimed compounds had two carbon atoms between two sulfur atoms, whereas the prior art ring structures had either one or three carbon atoms between two sulfur atoms. The court held that although the prior art compounds were not true homologs or isomers of the claimed compounds, the similarity between the chemical structures and properties is sufficiently close that one of ordinary skill in the art would have been motivated to make the claimed compounds in searching for new pesticides). In *re Gyurik*, 201 USPQ 552, 596 F2d 1012 on page 557 states: "In obviousness rejections based on close similarity in chemical structure, the necessary motivation to make a claimed compound, and thus the *prima facie* case of obviousness, rises from the expectation that compounds similar in structure will have similar properties." In this case, it is expected that compounds of general structure I taught by Ishida et. al. and Centaureidin of the instant application, differing by only one $-CH_3$ group, would have similar chemical, physical and biochemical properties.

At the time of the invention, it would have been *prima facie* obvious for a person of ordinary skill in the art to use Centaureidin, , for the treatment of skin disorders, since Centaureidin has a similar structure than the compounds of formula I described by Ishida et. al., thus resulting in the practice of claim 8, with a reasonable expectation of success

Claim 10, further limits claims 7 or 8, wherein the skin preparation for external use is a cosmetic. For claim 10, Ishida et. al further teach that the composition of formula I is a cosmetic composition (see paragraphs [0006] and [0007]).

At the time of the invention, it would have been *prima facie* obvious for a person of ordinary skill in the art to use compounds of formula I as a cosmetic as described by Ishida et. al for the treatment of skin disorders, thus resulting in the practice of claim 10, with a reasonable expectation of success.

Claim 9, further limits claims 7 or 8, wherein the skin preparation for external uses alleviates dyschromatosis on which tyrosine inhibitors have insufficient effect.

Ishida et. al. teach all the limitations of claim 1, except for the specific treatment of dyschromatosis. However, since dyschromatosis is a skin disease (anomalous skin pigmentation) and since Ishida et. al. teach that the compounds of formula I have an effect on skin whitening and treat skin darkening, at the time of the invention, it would have been *prima facie* obvious for a person of ordinary skill in the art to treat dyschromatosis with the instant compound of formula I, thus resulting in the practice of claim 9, with a reasonable expectation of success.

Claim 11, further limits claim 9, wherein the skin preparation for external use is a cosmetic. For claim 11, Ishida et. al further teach that the composition of formula I is a cosmetic composition (see paragraphs [0006] and [0007]).

At the time of the invention, it would have been *prima facie* obvious for a person of ordinary skill in the art to use compounds of formula I as a cosmetic as described by Ishida et. al for the treatment of skin disorders, thus resulting in the practice of claim 11, with a reasonable expectation of success.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MARCOS SZNAIDMAN whose telephone number is (571)270-3498. The examiner can normally be reached on Monday through Thursday 8 AM to 6 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sharmila G. Landau can be reached on 571 272-0614. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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/MARCOS SZNAIDMAN/

Examiner, Art Unit 1611

July 22, 2008

/Sharmila Gollamudi Landau/

Supervisory Patent Examiner, Art Unit 1611